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## Japan

### Sanitary/Phytosanitary/Food Safety

### Second Draft of New MRL Positive List Open for Public Comment

**2004**

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U.S.Embassy

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**Report Highlights:**

The Japanese Ministry of Health, Labor and Welfare released the Second Provisional Draft of Maximum Residue Limits (MRLs) on August 20. This list is open for public comment until November 30, 2004.

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Includes PSD Changes: No  
Includes Trade Matrix: No  
Unscheduled Report  
Tokyo [JA1]  
[JA]

## Background

The Ministry of Health, Labor and Welfare (MHLW) is in the process of implementing a "positive list system" of allowable chemical residues. This process is scheduled to be completed by May 2006. This system will prohibit the distribution of foods that contain agricultural chemicals if maximum residue limits (MRLs) for that chemical have not been established. MHLW released the First Draft of Provisional MRLs for public comment in October of 2003. The details were explained in GAIN reports JA3071 and JA4056.

Responses to major comments on the First Draft of Provisional MRLs can be found at: <http://www.mhlw.go.jp/english/topics/mrls/second/index.html>, responses to Embassy comments are scheduled to be sent to the embassies directly by September 10, 2004. Responses to individual comments can be found on the MHLW website at: <http://www.mhlw.go.jp/topics/bukyoku/iyaku/syoku-anzen/zanryu2/040820-2.html> in Japanese only.

## Second Draft of MRL "Positive List" Released

The Ministry of Health Labor and Welfare (MHLW) released the second draft of MRL on August 20, 2004 and held a meeting on September 2, 2004 to explain some of the changes.

Translations of the second draft are available in English at:  
<http://www.mhlw.go.jp/english/topics/mrls/second/index.html>

And in Japanese at:  
<http://www.mhlw.go.jp/topics/bukyoku/iyaku/syoku-anzen/zanryu2/index.html>

The index uses symbols to show where changes have been made. The meaning of the symbols are identified on page 11 of the index. It should be noted that in cases where more than one type of change was made to a chemical, just a circle was used in order to save space. Changes are indicated in the actual lists in bold lettering.

Also on this site you can find links to the following related documents, which are also open for public comment:

- Explanation of the Food Sanitation Law establishing a positive list:

To view this, follow the link to "level to be determined by the Minister of Health, Labour and Welfare, at the Pharmaceutical Affairs and Food Sanitation Council's advice, as that having no potential to cause damage to human health"

- Section on substances that have no potential to cause damage to human health, and which therefore have no set MRL but that will be allowed in Japan. These substances include some food additives, insecticides, biocides, plant growth regulators, animal drugs, and adhering agents.

To view this, follow the link to "substances to be determined by the Minister of Health, Labor and Welfare as those that apparently have no potential to cause damage to human health"

## Instructions For Public Comments

Comments can be sent **until November 30, 2004**

via mail to : Standards and Evaluation Division  
Department of Food Safety  
Ministry of Health, Labour and Welfare  
1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo  
100-8916, JAPAN

or via e-mail to: [positivelist@mhlw.go.jp](mailto:positivelist@mhlw.go.jp)

MHLW asks that comments:

- 1) Include the title, "Comments on the **second** draft of provisional MRL's" (the instructions say first draft but that is a mistake)
- 2) Include rationale for given comments and any underlying documents or data to support this rationale
- 3) Be submitted in Japanese if possible
- 4) Include the name (or company name), address, and occupation of submitting party

Purely clarification questions can also be directed to the U.S. Embassy, Tokyo at [AgTokyo@fas.usda.gov](mailto:AgTokyo@fas.usda.gov). If the comments are sent by November 15, the Embassy can try to get a response back before the end of the public comment period. Also, in order to keep aware of industry concerns, the U.S. Embassy, Tokyo would appreciate being copied on all comments being sent. These copies can be sent to:

[AgTokyo@fas.usda.gov](mailto:AgTokyo@fas.usda.gov)

or

Agricultural Attache  
U.S. Embassy Tokyo  
Unit 45004 Box 226  
APO, AP 96337-5004

This is for informational purposes only and will not count as official comments. Please send all official comments to the MHLW contact listed above.

### Next Steps

The Subcommittee on Pesticides and Veterinary Drugs will conduct further discussion before the provisional MRLs are finalized, taking the obtained comments into consideration. In addition, MHLW will ask the Food Safety Commission for comments on the section titled "level to be determined by the Minister of Health, Labor, and Welfare, at the Pharmaceutical Affairs and Food Sanitation Council's Advice, as that having no potential to cause damage to human health". MHLW will then notify the WTO in accordance with the necessary formalities, and also seek public comments on the final draft provisional MRLs. All products sold in Japan, including imports, will have to comply with the current final list or the provisional MRL, beginning in May 2006. Any residues not on the provisional or final lists of chemicals will be illegal after May 2006.

### Other Announcements

At the September 2 meeting, MHLW also announced the designation of Propanol as an authorized food additive, to be used for no purposes other than flavoring. This proposal is open for public comment until September 23, 2004. More details will be published in a future GAIN report.